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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/786,959

02/25/2004

William Toreki

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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

08/25/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/786,959	Applicant(s) TOREKI ET AL.	
	Examiner JAMES W. ROGERS	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 60,61,67,68,71 and 72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 60-61,67-68 and 71-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Any rejection from the previous office action filed 03/04/2009 not addressed below has been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 61 is rejected under 35 U.S.C. 102(b) as being anticipated by Schafer et al. (US 4,617,186), this new rejection was necessitated by applicants amendments to the claims.

Shafer teaches a sustained release drug delivery system which utilizes cationic polymeric quaternary ammonium compounds (polyquat) in combination with anionic drugs such as the anti-inflammatories ketoprofen and suprofen. See abstract and claims. The drug delivery system was used to treat various eye conditions treatable by an ophthalmic delivery system; the examiner considers an ophthalmic injury as a chronic wound. Regarding applicants limitation on the substrate being a woven, nonwoven, solid or flexible mass, Shafer teaches that the drug delivery system is a viscous polymer system which is within the scope of a flexible mass. It is noted by the examiner that the substrate as claimed is not necessarily a separate component from the polymer and drug since applicants defined the substrate as containing the polymer and anionic drug itself.

Claims 61 and 71 are rejected under 35 U.S.C. 102(b) as being anticipated by Somasundaran et al. (US 5,476,660)

Somasundaran teaches deposition of anionic active agents including antimicrobials and anti-acne agents to surfaces such as human skin, hair, oral surfaces and fabrics using carrier particles containing cationic polymers, preferably polyquats. See abstract, col 2 lin 19-37, col 4 lin 31-47, col 6 lin 10-43, col 7 lin 18-25 and claims. The examiner considered the entire particle which is solid mass as meeting the claimed substrate. The examiner further considered treating acne within the scope of treating chronic wounds. Regarding claim 71, Somasundaran teaches the use of polyquat 7 which is a polymer comprised of monomeric units of diallyldimethylammonium chloride.

Response to Arguments

Applicant's arguments filed 06/04/2009 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 61 and 70-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Batich et al. (US 2002/0177828) in view of Ward et al. (US 5,575,993), for the reasons set forth in the previous office action filed 03/06/2008.

Applicants assert that the secondary reference Ward does not teach or suggest an anionic antimicrobial compound in association with a quaternary ammonium polymer to achieve extended release as claimed.

The relevance of this assertion is unclear, since by combination the references above disclose the same cationic polymer in combination with an anionic antimicrobial any property of such a polymer composition will also be the same.

Applicants assert that Batich and Ward are nonanalogous art since Ward's polymers are leachably bound to the substrate since they could be washed off after use.

The relevance of this assertion is also unclear. As noted in previous office actions Ward was used as a secondary reference for its disclosure that it was already known in the art that anionic antimicrobial compounds could be associated to cationic polymers. Since Batich describes cationic polymers that as applicants purport are non-leachable and Ward teaches that cationic polymers were well known to be capable of releasing anionic drugs, applicant's claimed method of treatment comprising applying a cationic polymer with an ionically associated with an antimicrobial could have been obvious. As detailed in the previous action dated 03/04/2009 and incorporated herein applicants assertion that the polymer is bound to a substrate material does not preclude the Ward reference from reading on their claims.

Claims 60,64-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Batich et al. (US 2002/0177828) in view of Schoenfeldt et al. (US 2002/0172708) and in further view of Voorhees et al. (US 2004/0235950 A1), for the reasons set forth in the previous office action filed 03/06/2008.

Before the examiner comments on applicants arguments he notes that as detailed within applicants own specification within US 20050033251 A1 at paragraph [0092] it states that both GM1489 and the C-terminal carboxylic acid form of ilomastat

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are both anionic at physiological pH. Since Voorhees teaches the use of GM1489 and that reference it is obviously combinable with Batich and Schoenfeldt as detailed previously the new limitation that the MMPI is anionic is considered met.

Applicants assert that the secondary reference Schoenfeldt teaches away from the use of quaternary ammoniums polymers as cationic groups.

Schoenfeldt as disclosed previously was used as a secondary reference for its disclosure that cationic polymer compositions were well known to contain MMPI and the reference does not have to recite all of applicants claimed features on its own merit. Schoenfeldt clearly recites that the polyionic polymer contains at least one cationic group which includes amines, a cationic amine is an ammonium ion (which includes protonated substituted amines), and these polymers can incorporate the claimed ilomastat active ingredient. Disclosing cationic amines hardly teaches away from quaternary ammonium ions since they are similar functional groups, differing only in the number of substituted alkyl groups on the amine nitrogen. Thus the examiner concludes that since the polymers of Schoenfeldt and Batich are at least related to ammonium containing polymers, one of ordinary skill in the art would have a reasonable expectation of success in combining the references to make a quaternary ammonium polymer as described in Batich while containing an MMPI.

Applicants assert that clearly neither Schoenfeldt nor Batich disclose the use of an anionic MMPI or an ionic association as claimed.

The examiner respectfully disagrees. As recited above Voorhees describes GM1489 which is an anionic MMPI at physiological pH. It is acceptable to conclude that

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upon administration to a wound the MMPI is anionic and since it is contained within a cationic polymer there will at least be some ionic association.

Applicants lastly assert that none of the references above discuss extended releaser properties of the materials.

Since by combination the references disclose the same material claimed by applicants the properties of such as material will be the same.

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP §706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618